SAMPLE FORMS	FORM #
SOP Chapter 1	
Letter of Appointment of RERB Members	1D
Letter of Appointment of RERB Chair	1A
Letter of Appointment of RERB Vice-Chair	1B
Letter of Appointment of RERB Secretary	1C
Letter of Appointment of Independent Consultant	1E
Confidentiality and Conflict of Interest Agreement	2
Curriculum Vitae	3
Terms of Reference (RERB Members)	4A
Terms of Reference (Independent Consultants)	4B
Training Record of RERB Member	5
SOP Chapter 2	
Application Form for Protocol Review	6A
Checklist of Documents Submitted for Protocol Review	6B
Protocol Summary Sheet	7
Reviewer's Protocol Evaluation Form	8
Informed Consent Evaluation Form	9
Child Assent Form	10
Waiver of Informed Consent	11
Resubmitted Protocol Form	12
Application for Withdrawal of Protocol Submission	13
Notification of RERB Decision	14
Approval Letter	15
Application for Exempt from Review	16
Certificate for Exempt form Review	17
SOP Chapter 3	
Serious Adverse Event Report Form	18
Protocol Amendment Review Form	19
Progress Report Form	20
Reminder Letter for Continuing Review	21
Continuing Review Application Form	22
Final Report Form	23
Protocol Deviation/ Non-compliance/ Violation Form	24
Request/ Query Record	25
Site Visit Report	26

LETTER OF APPOINTMENT OF CHAIR (FORM 1A)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as Chair of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As Chair of the RERB, your specific responsibilities include:

- Finalize and approve the agenda and preside in all RERB meetings.
- Conduct a preliminary review of all protocols and decide on the nature of review – expedite, exempt or full board
- Assign primary reviewers to initial protocols submitted
- Ensure that a final decision on all protocols reviewed is made and break a tie whenever a deadlock in RERB voting occurs
- Sign the following communications: Notice of Meetings, Notice of Action to Principal Investigators and Sponsors
- Represent Chinese General Hospital and Medical Center in ethics-related symposia or meetings that require institutional participation
- Ensure that appropriate decisions/actions are made by the RERB on issues that include but are not limited to research participants complaints, findings of non-compliance during an FDA audit, loss of records or study drugs, higher than expected occurrences of adverse events, unexpected adverse events that are at least possibly related to the study, drug accountability problems, unanticipated change in Principal Investigator, etc.
- Submit annual reports on the accomplishments of the RERB to PHREB
- Communicate decisions of the RERB to research proponents
- Ensures that all RERB members receive orientation and undergo basic Research Ethics training immediately after their appointment and continuing education thereafter
- Prepares budget plan for the RERB

These are addition to your roles and responsibilities as member:

- Participate in regular RERB meetings
- Review, discuss, and consider all research proposals submitted to the RERB for evaluation and approval
- Assess serious adverse event reports arising from the trials and recommend appropriate action/s
- Review the progress reports and monitor ongoing trials as appropriate

- Check progress and final reports of trials
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

_____
Director, Department of Medical Education and Research
CGHMC

Conforme:

_____ _____
(Print name & sign) Date

LETTER OF APPOINTMENT OF VICE-CHAIR (FORM 1B)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as Vice-Chair of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As Vice-chair of the RERB, your specific responsibilities include:

- Be appointed by the Chair and selected based on experience and expertise from among the current RERB members
- Have the authority to perform all the duties of the Chair when the latter is unavailable or unable to perform them
- Perform other tasks as delegated by the Chair

These are addition to your roles and responsibilities as member:

- Participate in regular RERB meetings
- Review, discuss, and consider all research proposals submitted to the RERB for evaluation and approval
- Assess serious adverse event reports arising from the trials and recommend appropriate action/s
- Review the progress reports and monitor ongoing trials as appropriate

- Check progress and final reports of trials
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

_____
Chair, Research Ethics Review Board
CGHMC

_____
Director, Department of Medical Education and Research
CGHMC

Conforme:

_____ _____
(Print name & sign) Date

LETTER OF APPOINTMENT OF SECRETARY (FORM 1C)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as secretary of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). The appointment is in accordance with the CGHMC RERB Standard Operating Procedures. As secretary of the RERB, your specific responsibilities include:

- Review minutes of the meeting
- Supervise the secretariat in the documentation of files
- Accurately record and review all minutes of the meeting of the RERB

These are addition to your roles and responsibilities as member:

- Participate in regular RERB meetings
- Review, discuss, and consider all research proposals submitted to the RERB for evaluation and approval
- Assess serious adverse event reports arising from the trials and recommend appropriate action/s
- Review the progress reports and monitor ongoing trials as appropriate

- Check progress and final reports of trials
- Maintain confidentiality of the documents and deliberations of RERB meetings
- Declare any conflict of interest
- Participate in continuing educational activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

_____
Chair, Research Ethics Review Board
CGHMC

_____
Director, Department of Medical Education and Research
CGHMC

Conforme:

_____ _____
(Print name & sign) Date

LETTER OF APPOINTMENT OF RERB MEMBER (FORM 1D)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

We are pleased to appoint you as member of the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB). The appointment is in accordance with the CGHMC RERB Standard Operating Procedures.

As a member, you will have the following roles and responsibilities:

1. Participate in regular RERB meetings
2. Review, discuss, and consider all research proposals submitted to the RERB for evaluation and approval
3. Assess serious adverse event reports arising from the trials and recommend appropriate action/s
4. Review the progress reports and monitor ongoing trials as appropriate
5. Check progress and final reports of trials
6. Maintain confidentiality of the documents and deliberations of RERB meetings
7. Declare any conflict of interest
8. Participate in continuing educational activities in research methodology and research ethics

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

_____
Director, Department of Medical Education and Research
CGHMC

Conforme:

_____ _____
(Print name & sign) Date

APPOINTMENT LETTER OF INDEPENDENT CONSULTANT (FORM 1E)

Date

Dr.
(Title/Affiliation)

Dear Dr. ,

The Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) is inviting you to be an Independent Consultant, in your capacity as a (EXPERTISE), to provide expert review of study protocols which require scientific or medical expertise not represented in the current composition of the board or those which board has ascertained to require additional expert review.

The responsibilities of an Independent Consultant are as follows:

1. Review, discuss, and evaluate research proposals assigned and accomplished study assessment forms
2. Maintain confidentiality of the documents and deliberations of RERB meetings
3. Declare any conflict of interest

If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the CGHMC RERB secretariat. Kindly sign, date, and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.

Sincerely yours,

_____
Director, Department of Medical Education and Research
CGHMC

Conforme:

_____ _____
(Print name & sign) Date

CONFIDENTIALITY AND
CONFLICT OF INTEREST AGREEMENT (Form 2)

Know all Men by these Presents:

In view of the appointment of (TITLE, NAME, INSTITUTIONAL AFFILIATION), as a member of the Chinese General Hospital and Medical Center Institutional Review Board (RERB), and hereinafter referred to as the *Undersigned*, and

Whereas:

The *Undersigned* has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the appointment of the *Undersigned* as a member of the CGHMC RERB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest;

the fundamental duty of an RERB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the CGHMC RERB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed RERB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the RERB to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the Undersigned in conjunction with and/or in

the course of the performance of his/her duties as a member/independent consultant of the CGHMC RERB.

Any written information provided to the *Undersigned* that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the RERB.

As such, the *Undersigned* agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the *Undersigned* agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The *Undersigned* further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the *Undersigned* confirms that her performance of this agreement is consistent with Chinese General Hospital and Medical Center policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the RERB to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the RERB that no member/consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the RERB.

The *Undersigned* will immediately disclose to the Chair of the CGHMC RERB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the RERB, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an RERB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chair. The request must contain evidence that substantiates the claim that a conflict exist with the RERB member(s) in question. The RERB may elect to investigate the applicant's claim of the potential conflict.

When a member/consultant has a conflict of interest, the member should notify the Chairperson and may not participate in the RERB review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

A member/independent consultant is involved in a potentially competing research program.

Access to funding or intellectual information that may provide an unfair competitive advantage.

A member's/independent consultants' personal biases may interfere with his or her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[To the *Undersigned:* Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the CGHMC RERB. A copy will be given to you for your records.]

In the course of my activities as a member of the CGHMC RERB, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an RERB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accepted the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Title/Name Date

_____ _____

CGHMC RERB Chair Date

CURRICULUM VITAE (FORM 3)

Last name		First Name	
Residence Address		Office Address	
Email address		Contact No.	(Res) (Ofc)
Highest Educational Attainment		Mobile No.	
Research and Ethics Training/s			
WORK EXPERIENCE (Please include year)			
A. Occupation			
B. Previous work experience			
C. Present work			
D. Research–related experience			
How do you prefer to be contacted by our Secretariat? (Put a checkmark to all that apply) ☐email address ☐res no. ☐office no. ☐mobile no.			
To be filled up by Secretariat:			
Position in the IRB – Inclusive year of 1st appointment			
Position in the RERB – Inclusive year of 2nd appointment			

TERMS OF REFERENCE (Form 4A)
(RERB MEMBERS)

Purpose

The Chinese General Hospital and Medical Center (CGHMC) Research Ethics Review Board (RERB) is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees.

Roles and Responsibilities

The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection. In accordance to provisions set forth in the national and international guidelines, it has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance of its researchers with all relevant procedures after approval of trials.

Membership

While the RERB remains under the authority of the DMER, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines.

The CGHMC RERB shall be composed of a pool of at least 8 members.

The RERB membership shall allow for multidisciplinary and multisectoral representation to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations. Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. The RERB also includes a person who will represent the interest and concerns of the community, have at least one member who is in a non-medical/non-scientific area, and one who is non-affiliated to the institution. It shall aim for gender balance in its membership, with representation from both old and young generation. An independent consultant may also be invited to provide expert opinion and expertise to protocols under review, with no voting privilege.

Appointment of Members and Terms of Office

RERB members shall nominate qualified candidates for new members to the Chair. The Director of DMER selects from the list of nominees for RERB members and issues an appointment letter.

Members are appointed for a maximum period of two (2) years on the initial appointment. The appointments may be renewed by the Appointing Authority for every three (3) years.

Training of Members

It is the responsibility of all the RERB officers, members and staff to have themselves educated and trained regularly. Initial research ethics training shall consist of basic training in research ethics principles, GCP, and in-house mentoring in RERB standard operating procedures (SOP). In addition, they should be provided with external training opportunities at least once a year from information on courses/conferences gathered from various media channels in coordination with the Secretariat.

Review of Research Proposals

The CGHMC RERB accepts the following protocols for review: 1) CGHMC funded researches, 2) researches done in CGHMC by medical house staff, 3) research proposals submitted by CGHMC personnel for thesis defense, 4) industry sponsored researches to be conducted by CGHMC active/visiting medical staff to be conducted off-site (in the event the institution does not have ethics review board in place). In consideration to multi-center trials or studies, each Center/trial site has to have an independent or its own RERB approval for the said protocol.

Other than obtaining RERB approval, researches to be conducted by trainees that entail retrospective review of charts/medical records (with no actual participant/subject contact in whatever manner) will need to be approved by the Medical Director prior to implementation. All clinical study agreement (CSA) of externally supported/funded studies/trials should undergo approval by the Legal Division of the Hospital. RERB approval letter will not be released until CSA is approved by the office of the legal counsel.

Protocols submitted for RERB review (either for full board or expedited reviews) should follow the detailed steps set forth in the SOP. The RERB conducts regular reviews of approved protocols until end-of-study period. The Secretariat keeps close communication with the principal investigator for any concerns that need further clarification or actions.

Meetings

Monthly RERB meeting is held to discuss all concerns related to new protocols and ongoing studies. Notice of meeting as well as agenda set for the date will be closely coordinated to all by the Secretariat. For each meeting, an invitation to more than half of the general membership shall constitute a quorum, which includes community representative/lay member who is independent of

the institution or research site. In any case that an RERB member has conflict of interest to a particular protocol, s/he may give insights/inputs during deliberation but should inhibit her/himself from voting.

Post Approval Responsibilities

The RERB will continue to monitor approved projects in terms of compliance with national and international as well as local ethical approval. The RERB requires researchers to provide regular reports (frequency depends upon manner of review – full board or expedited review) and on completion of the study. It may request for additional information from the researchers on any relevant aspects of the project at any time. It will also require the researchers to report any form of protocol amendments, serious adverse events, protocol violation and deviation, early termination, as well as participant's requests or queries as soon as possible. Appropriate mechanism for site monitoring and random audits are also in place.

Amendments to the Terms Of Reference

The Board may amend the Terms of Reference at anytime or from time to time.

I have read and accepted the aforementioned Terms of Reference as explained above.

(Signature above Printed Name)

CGHMC RERB Member
Date:

TERMS OF REFERENCE (Form 4B)
(INDEPENDENT CONSULTANTS)

Purpose

The Chinese General Hospital and Medical Center (CGHMC) Research Ethics Review Board (RERB) is an independent body created by the CGHMC Committee on Research under the Department of Medical Education and Research (DMER) for the purpose of promoting ethical and quality research among the hospital staff and trainees.

Roles and Responsibilities

The main responsibility of the CGHMC RERB is to safeguard the rights, safety, and well-being of human participants involved in health-related research within applicable laws and regulations and to provide public assurance of that protection. In accordance to provisions set forth in the national and international guidelines, it has the sole authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance of its researchers with all relevant procedures after approval of trials.

Membership

While the RERB remains under the authority of the DMER, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines.

The CGHMC RERB shall be composed of members from various disciplines and sectors to foster a comprehensive and efficient review of research activities conducted by the CGHMC staff and non-affiliated organizations. Relevant experts in various fields of science will comprise general membership, including non-medical/non-scientific/non-affiliated member to the institution. It shall aim for gender balance in its membership, with representation from both old and young generation.

An independent consultant is invited to attend the RERB meeting, present his/her assessment, and participate in the discussion but without voting rights. The report becomes a permanent part of the study file.

Appointment of Independent Consultant and Terms of Office

The RERB Board members nominate independent consultants based on their specialties to help review research where the RERB lacks expertise. The DMER Director appoints independent

consultants for initial period of two (2) years, with an option to be reappointed thereafter depending on the voluntary approval of the consultant.

Once independent consultant signs the terms of appointment, the Secretariat will ask him/her to provide the following: an updated curriculum vitae (Form 3), a signed Terms of Reference (Form 4B), a signed Confidentiality/Conflict of Interest (Form 2). The Secretariat then keeps copies of pertinent documents.

Termination of Services

Independent consultant's services may be terminated by either the consultant or by the DMER Director upon recommendation of the Board.

Upon termination of the independent consultant's services, the Secretariat shall ensure that all the necessary documents is completely filed up with the other administrative documents.

Amendments to the Terms Of Reference

The Board may amend the Terms of Reference at anytime or from time to time.

I have read and accepted the aforementioned Terms of Reference as explained above.

(Signature above Printed Name)
Independent Consultant
CGHMC RERB
Date:

TRAINING RECORD OF RERB MEMBER (FORM 5)

Last name		First name		
BASIC COURSES	**ORGANIZER**	**VENUE**	**DATE**	**FUNDING SOURCE**
1. GCP Training				
2. Research Ethics				
3. RERB Standard Operating Procedures (SOP)				
CONTINUING ETHICS EDUCATION: ***(incl Research Ethics Workshops, Conferences, Meetings, Lectures)***	**ORGANIZER**	**VENUE**	**DATE**	**FUNDING SOURCE**
1.				
2				
3				
4				
5				

APPLICATION FORM FOR PROTOCOL REVIEW (FORM 6A)

CGHMC RERB Protocol Number		Sponsor Protocol No:	
Submission Date			
Protocol Title:			
Principal Investigator			
Contact details:	☏:		
	Mobile:		
	Fax:		
	Email address:		
Sponsor:			
PI Conflict of Interest/ Declaration (Relationship with Sponsor)	Are you a regular employee of the sponsor? ☐ Yes ☐ No		
	Did you do consultancy or part time work for the sponsor? ☐ Yes ☐ No		
	In the past year, did you receive P250,000 or more from the sponsor? ☐ Yes ☐ No		
	Other ties with the sponsor		
By signing the application form, I undertake to address my competing interests, uphold scientific integrity, respect and protect human subjects during the conduct of my research in this institution.			
PI Signature:			

CHECKLIST OF DOCUMENTS SUBMITTED FOR PROTOCOL REVIEW (FORM 6B)

CGHMC RERB PROTOCOL NO:		**Sponsor Protocol No.**
PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		

Documents submitted: (Please check all applicable)

Documents
☐**Protocol**
☐**Patient information form**
☐**Informed consent form (English and Tagalog Version)**
☐**Assent Form in English and Tagalog (for studies involving minor and relevant subjects incompetent to sign an ICF**
☐**Advertisement**
☐**Investigator's brochure**
☐**Protocol summary**
☐**Ethical Considerations – description/statement of compliance with ethical principle**
☐**Data Protection Plan**
☐**Data Collection Forms/ Case report forms (CRFs)**
☐**Research team list**
☐**Curriculum vitae (CV) (all team members)**
☐**valid GCP certificates (team) updated (3 years validity)**
☐**Study budget**
☐**Revised protocol**
☐**Revised consent form**
☐**Amendments**
☐**Technical Review Approval**
☐**Insurance certificate (if applicable)**
☐**FDA approval (if applicable)**
☐**Others (Please specify)**

PROTOCOL SUMMARY SHEET (Form 7)

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Date Submitted			
Title:			
Principal Investigator		Sponsor	
Rationale			
Objectives			
Study Design/ Methodology			
Inclusion Criteria			
Exclusion Criteria			
Data Analysis Plan			
Study Outcomes			

REVIEWER'S PROTOCOL EVALUATION FORM (FORM 8)

CGHMC RERB Protocol No.		**Sponsor Protocol No.**	
Date Submitted			
Protocol Title			
Principal Investigators:		Contact details:	
Department:			
Co-investigator(s):		**Contact details:**	
Overall/Total No. of Participants (onsite and off-site):	**Total no. of onsite participants:**	**No. of Study sites (if applicable):**	
Sponsor		**Contact Person/ contact details:**	
Clinical Research Organization		**Contact Person/ contact details**	
Duration of the Study (mos/years):		**Status:** ☐ New Protocol ☐ Amended Protocol (Pls state version number/date)	
Reviewers:			
Type of the Study	☐ Intervention ☐ Observational study ☐ Document review ☐ Individual based	☐ Epidemiology ☐ Genetic ☐ Social Survey ☐ Others, specify	
Review Status	☐ Full Board	☐ Expedited	
Description of the study in brief: (Mark whatever applies to the study.)			
☐ Randomized	☐ Drug	☐ Use of Genetic materials	
☐ Double blind	☐ Medical device	☐ Multicenter study	
☐ Single blind	☐ Vaccine	☐ Global protocol	

☐Open label	☐ Diagnostics	☐ Sponsorinitiated
☐ Observational	☐ Questionnaire/Survey	☐Investigator Initiated

A. PROTOCOL DOCUMENT REVIEW (to be filled up by reviewer)

ASSESSMENT POINTS	YES	NO	N/A	REVIEWER COMMENTS
1. SCIENTIFIC DESIGN				
1.1 Objectives Review of viability of expected output				
1.2 Literature Review Review of results of previous animal/human studies showing known risks and benefits of intervention, including known adverse drug effects, in case of drug trials				
1.3 Research Design Review of appropriateness of design in view of objectives				
1.4 Sampling Design Review of appropriateness of sampling methods and techniques				
1.5 Sample Size Review of computation of sample size				
1.6 Statistical Plan Review of appropriateness of statistical methods to be used and how participant data will be summarized				
1.7 Data Analysis Plan Review of appropriateness of statistical and non-statistical methods of data analysis				
1.8 Inclusion criteria Review of precision of criteria both for scientific merit and safety concerns; and of equitable selection				
1.9 Exclusion criteria Review of criteria precision both for scientific merit and safety concerns; and of justified exclusion				

1.10 Withdrawal criteria Review of criteria precision both for scientific merit and safety concerns				
2. CONDUCT OF THE STUDY				
2.1 Specimen handling Review of specimen storage, access, disposal, and terms of use				
2.2 PI qualifications Review of CV and relevant certifications to ascertain capability to manage study related risks				
2.3 Suitability of Site Review of adequacy of qualified staff and infrastructure				
2.4 Duration Review of length/extent of human participant involvement in the study				
3. ETHICAL CONSIDERATIONS				
3.1 Conflict of Interest Review of management of conflict arising from financial, familial, or proprietary considerations of the PI, sponsor, or the study site				
3.2 Privacy and confidentiality Review of measures or guarantees to protect privacy and confidentiality of participant information as indicated by data collection methods including data protection plans				
3.3 Informed consent process Review of application of the principle of respect for persons, who may solicit consent, how and when it will be done; who may give consent especially in case of special populations like minors and those who are not legally competent to give consent, or indigenous people which require additional clearances				
3.4 Vulnerability				

Review of involvement of vulnerable study populations and impact on informed consent (see 3.3). Vulnerable groups include children, the elderly, ethnic and racial minority groups, the homeless, prisoners, people with incurable disease, people who are politically powerless, or junior members of a hierarchical group				
3.5 Recruitment Review of manner of recruitment including appropriateness of identified recruiting parties				
3.6 Assent Review of feasibility of obtaining assent vis à vis incompetence to consent; Review of applicability of the assent age brackets in children: 0-under 7: No assent; 7-under 12; Verbal Assent 12-under 15; Simplified Assent Form 15-under 18; Co-sign informed consent form with parents				
3.7 Risks Review of level of risk and measures to mitigate these risks (including physical ,psychological, social, economic), including plans for adverse event management; Review of justification for allowable use of placebo as detailed in the Declaration of Helsinki (as applicable)				
3.8 Benefits Review of potential direct benefit to participants; the potential to yield generalizable knowledge about the participants' condition/problem; non-material compensation to participant (health education or other creative benefits), where no clear, direct benefit from the project will be received by the participant				
3.9 Incentives or compensation				

Review of amount and method of compensations, financial incentives, or reimbursement of study-related expenses				
3.10 Collaborative study terms of Reference Review of terms of collaborative study especially in case of multi-country/multi-institutional studies, including intellectual property rights, publication rights, information and responsibility sharing, transparency, and capacity building				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision	
	☐ Major Revision/ Resubmission	☐ Disapproved	
Comments (Identify items for revision)			
Reviewer's Name		Date	
Signature			

INFORMED CONSENT EVALUATION FORM (FORM 9)

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Principal Investigators:		Co-investigator/s:	

INFORMED CONSENT DOCUMENT REVIEW	**YES**	**NO**	**N/A**	**REVIEWER COMMENTS**
1. Does the Informed Consent document state that the procedures are primarily intended for research?				
2. Are procedures for obtaining Informed Consent appropriate?				
3. Does the Informed Consent document contain comprehensive and relevant information?				
4. Is the information provided in the protocol consistent with those in the consent form?				
5. Is the expected duration of the study stated?				
6. Is the approximate number of participants stated?				
7. Are study related risks mentioned in the consent form?				
8. Is the language in the Informed Consent document understandable?				
9. Is the Informed Consent translated into the local language/dialect?				

10. Is there adequate protection of vulnerable participants?				
11. Are the different types of consent forms (assent, legally acceptable representative) appropriate for the types of study participants?				
Should assent be required? ☐verbal assent(7 – 11 y/o) ☐simplified assent(12-14 y/o) ☐co-sign (15 – 17 y/o)				
12. Is there a description of any reasonably forseeable risks or discomfort to the subject?				
13. Is there a description of any benefits to the subject or to others which may reasonably be expected from the research?				
14. Is there a disclosure of appropriate alternative procedures or courses of treatment, if any, might be advantageous to the subject?				
15. Are names and contact numbers from the research team and the RERB in the informed consent?				
16. Does the ICF mention privacy & confidentiality protection?				
17. Is there any inducement for participation?				
18. Is there provision for medical / psychosocial support?				
19. Is there provision for treatment of study-related injury?				
20. Is there provision for compensation?				

B. Recommendation

DECISION:	☐ Approval	☐ Minor Revision	
	☐ Major Revision/ Resubmission	☐ Disapproved	
Comments (Identify items for revision)			
Reviewer's Name		Date	
Signature			

CHILD ASSENT FORM (FORM 10)

This sample is intended to assist researcher son introducing the required elements of an assent form in a way that is considered simple and easy for a child to understand.

Study Title:

Investigator:

Sponsor:

We are doing a research study about **(*purpose in simple language)***. A research study is a way to learn more about people with a certain condition. We are therefore inviting you to participate in the study. If you decide that you want to be part of this study, you will be asked to **(*study description, including estimate time involved in participating).***
There are some things about this study you should know. These are **(*procedures, things that take a long time, other risks, discomforts, etc).***
Not everyone who takes part in this study will benefit. A benefit means that something good happens to the participant. We think these benefits might be **(*brief description on what is known)***.
If you do not want to be in this research study, we will tell you what other kinds of treatments that are currently available for you. **(*This statement applies to research projects that offer treatment or intervention.)***
When we are finished with this study, we will write a report about what was learned. The report will not include your name or that you were involved in the study.

You do not have to be in this study if you do not want to. Your doctor will not be mad at you. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

You can ask anything about the study that is not clear to you. If everything is clear to you and you decide you want to be in this study, please write and sign your name below.

I, _____, want to be in this research study.

_____ _____
(Sign your name here) (Date)

(Parts in Italics should be modified for your specific project. Other parts may need to be modified as well depending on your research methods.* It is very important that the language be appropriate to the subject's level of understanding; if the subject population includes a wide range of ages, it may be necessary to use more than one form. *)

REQUEST TO WAIVE WRITTEN AND VERBAL INFORMED CONSENT (Form 11)

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Protocol Title:			
Principal Investigators:		Co-investigator/s:	

I am requesting a waiver of written and verbal informed consent. I believe that this protocol is eligible for waiver or alteration of all required elements of informed consent because the protocol meets all of the following criteria:

1. **The risk to the subject's privacy is minimal.**
   The investigator of this study will use the minimum amount of protected health information necessary to conduct the research. This study will only need charts of eligible subjects. There will be no sensitive information (e.g. illegal drug use, sexual practices) to be collected. There is an assurance written below that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.
2. **This research cannot practicably be conducted without the use of the protected information.**
3. **This research cannot practicably be conducted without the waiver.**
   a. The number of research subjects proposed.
   b. Difficulty of obtaining individual authorization and time since last contact with the research subjects.

RESEARCH ASSURANCES:

As a principal investigator of the research described above, I make the following assurance to the Institutional Ethics Review Board regarding the use and disclosure of protected health information.

"The investigators and research staff who used the disclosed protected health information in connection with this research will not reuse the protected health information or disclose to any other person or entity other than those authorized to receive it, except:

1. As required by law,
2. For authorized oversight of the research study, or
3. For other research which the use or disclosure of protected health information would be permitted by the Privacy Rule"

_____ _____

Principal Investigator **Date**

RESUBMITTED STUDY PROTOCOL (Form 12)

RERB Protocol No.	Date of Submission
Protocol Title:	
Principal Investigator:	Contact No.
Date of Initial Submission:_____ ☐ 2nd Review date: _____	☐ 3rd Review date:_____
Initial Review Date:	Last Review Date:
Recommendations from last review:	Were the recommendations met (Yes/No)? Explain and highlight changes in the protocol submitted (Indicate page number where changes are made, if applicable)
1.	
2.	
3.	
4.	
5.	

Recommendation	Primary Reviewers:
☐ Approved ☐ Minor revision ☐ Major revision ☐ Disapproved	_____ Signature Date

Principal Investigator:_____ Date: _____

WITHDRAWAL OF PROTOCOL SUBMISSION APPLICATION (FORM 13)

Date Submitted:		
CGHMC RERB Protocol No:		Sponsor protocol No.
Title:		
Principal Investigator		Sponsor
Reason For Withdrawal of Protocol Submission		
RECOMMENDED ACTION: ☐No Further Action ☐Request Information: (Specify) ☐Recommend Further Action: (Specify)		**Type of Review** ☐Full Board ☐Expedited Meeting Date:
PRIMARY REVIEWER: _____ Signature over name **RERB CHAIR:** _____ Signature over name		_____ Date _____ Date

NOTIFICATION OF RERB DECISION (FORM 14)

Date _____

To: (Name of PI) _____
Affiliation

This is to inform you of the RERB decision related to your application for review of the following documents:

CGHMC RERB Protocol No.		Sponsor Protocol No.	

Type of Submission
- ☐ Initial review of Documents submitted
- ☐ Resubmission
- ☐ Amendment
- ☐ Others

Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			

Type of review ☐Expedited ☐Full Board Meeting
RERB Decision ☐Approved ☐Minor revisions required
☐Major revisions required ☐More information needed
☐Others

Actions required from PI:
1.
2.

RERB Chair Person	Name	Signature	Date

APPROVAL LETTER (FORM 15)

Date _____

This is to certify that the following protocol and related documents have been granted approval by the CGHMC RERB for implementation

CGHMC RERB Protocol No.		Sponsor Protocol No.	
Principal Investigator		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other Documents			
Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From _____ to _____	Frequency of continuing review
RERB Chair	Name	Signature	Date

Investigator Responsibilities after Approval:

- Submit document amendments for RERB approval before implementing them
- Submit on-site SAE/SUSAR reports to sponsor within 24 hours after notification of event, and to RERB within 7 days or as data is completed
- Submit progress report as part of CGHMC RERB continuing review process every 6 months and yearly for high-risk study, and yearly for low-risk study
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation/violation on timely manner
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research

Received by:
Name and Signature: _____ Date Received: _____

REVIEW EXEMPTION APPLICATION FORM (FORM 16)

Date Submitted:		
CGHMC RERB Protocol No:		Sponsor Protocol No
Title:		
Principal Investigator		Sponsor
Brief Description of the Project (Please give a brief summary of the nature of the proposal. Including objectives, rationale, participants' description, and procedures/ methods to be used in the project. Please also fill up Research Protocol Application Form (Form 6)		
State reasons why exemption from review is requested? ☐audits of educational practices ☐research on microbes cultured in the laboratory ☐research on immortalized cell lines ☐research on cadaver sor death certificates provided such research reveals no identifying personal data ☐Analysis of data freely available in public domain ☐Any other		
NAME OF PRINCIPAL INVESTIGATOR	SIGN / DATE	

CERTIFICATE OF EXEMPTION FROM REVIEW (FORM 17)

Date:

This is to certify that the following protocol and related documents have been reviewed and is hereby granted EXEMPTION FROM REVIEW by the Chinese General Hospital and Medical Center CGHMC RERB for implementation.

CGHMC RERB Protocol No:		**Sponsor Protocol No.**	
Title:			
Principal Investigator		**Sponsor**	
Protocol Version No		**Version Date**	
Other Documents			
RERB Chair	**Signature**	**Date**	

Received by:

Signature over printed name/ Date

SERIOUS ADVERSE EVENT REPORT FORM (FORM 18)

Whenever there is any SAE event in any research approved by the CGHMC RERB, it has to be reported by the principal investigator (PI) to the RERB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator: (Name)			
CGHMC RERB Protocol No.	Sponsor Protocol No.		
Date Submitted	Signature		
Study Title:			
Name of the study medicine/device:	Report Date: ☐ Initial ☐ Follow-up Onset Date:		
Sponsor:	Date of first use of drug/device:		
Title of the Report			
Subject's Number:	Age:	☐Male	☐ Female
Subject's history:	Laboratory findings:		
SAE:	Treatment Outcome: ☐ Resolved ☐ On-going		
Seriousness: ☐Death ☐Life Threatening Hospitalization: ☐Short-stay ☐Prolonged ☐Disability/Incapacitated ☐Congenital Anomaly ☐Others	Relation to ☐ Drug ☐Device Study ☐Not related ☐Possibly ☐Probably ☐Definitely related ☐Unknown		

Note: PI should attach standard SAE report form to this RERB form.

SECTION 2 (to be filled up by the designated SAE Subcommittee reviewer)

Document received by the RERB Secretariat	Signature	Date
Reviewer's Name/Signature:		Date: (dd/mm/yyyy)

Changes to the protocol recommended? Comments:	☐ Yes	☐ No
Changes to the informed consent form recommended? Comments:	☐ Yes	☐ No

RERB Final Action:

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Take note and no further action
- ☐ Others: _____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting

_____

Name of RERB Reviewer:	Signature	Date (dd/mm/yyyy)

PROTOCOL AMENDMENT REVIEW (FORM 19)

CGHMC RERB Protocol No.	Sponsor Protocol No	Date of Submission
PROTOCOL TITLE		
Principal Investigator	Sponsor	Contact Number

List of Amendments	Reasons
1. 2. 3. 4. 5. 6. 7.	

Comments of Primary Reviewers	Type of Review
	☐Full Board ☐Expedite Date of Meeting: _____

RERB Decision	Name/Signature of Chair	Date
☐Uphold approval ☐Need further information		

PROGRESS REPORT (FORM 20)

CGHMC RERB Protocol No.	Sponsor Protocol No.
Protocol Title	
Investigator: (Name and Signature)	Approval Date: (dd/mm/yyyy)
Annual Progress Report: *(Please indicate inclusive period):* Total number of screened subjects: Total number of randomized subjects: Total number of withdrawn patients: Total number of SAEs: Total number of lost to follow up: Total number of completed subjects:	
Submitted by:	Date Submitted: (dd/mm/yyyy)

To be filled up by RERB

Date Received:	Received by: (Printed Name/Signature)	
Primary Reviewers/Signature:		Date
Recommendations ☐ Approved ☐ Request further information ☐ Suspend or terminate the study ☐ Others: _____		Type of review: ☐ Expedited review ☐ Full board review Date of meeting: _____
RERB Final Decision:		
Certified by: Name of CGHMC RERB Chair	Signature	Date

CONTINUING REVIEW APPLICATION FORM (FORM 21)

CGHMC RERB Protocol No.	Sponsor Protocol No.
Protocol Title	
Investigator	Approval Date: (dd/mm/yyyy)

ACTION REQUESTED:

☐ Renew – New participant accrual to continue

☐ Renew – Enrolled participant follow up only

☐ Terminate – Protocol discontinued

Any amendment since last review? ☐ Yes ☐ No

(Discuss briefly)

Any change in participant population recruitment or selection criteria since the last review? (Explain the changes if any) ☐ Yes ☐ No

Any change in the Informed Consent process or documentation since the last review? (Please explain, if yes.) ☐ Yes ☐ No

Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Discuss and attach a narrative.) ☐ Yes ☐ No
Any unexpected complication or side effect noted since the last review? (Discuss and attach a narrative.) ☐ Yes ☐ No
Did any participant withdraw from this study since the last approval? (Reasons for withdrawal) ☐ Yes ☐ No
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.) ☐ Yes ☐ No
Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.
Summary of protocol participants: ☐ Reached the target number of participants approved by CGHMCRERB ☐ New participants recruited/enrolled since last review ☐ Total participants screened since protocol began ☐ Total participants enrolled and ongoing since the last review ☐ Total number of SAEs since the last review

☐Total number of participants withdrawn or terminated
ACCRUAL EXCLUSIONS ☐ None ☐ Male ☐ Female ☐Others (Specify) _____
Impaired participants ☐ None ☐Physically ☐Cognitively ☐ Both

To be filled up by RERB

Date Received:	Received by: (Printed Name/Signature)	
Primary Reviewers/Signature:		Date:
Recommendations ☐ Approved ☐ Request amendment to the protocol or the consent form ☐ Request further information ☐ Suspend or terminate the study ☐ Others: _____		Type of review: ☐ Expedited review ☐ Full board review Date of meeting: _____
RERB Final Decision:		
Certified by: Name of CGHMC RERB Chair	Signature	Date

REMINDER LETTER FOR CONTINUING REVIEW (FORM 22)

Date

Principal Investigator
Affiliation

RE: PROTOCOL CODE/ PROTOCOL TITLE

Dear Dr. ,

We wish to remind you that the RERB approval for the study protocol <Study Protocol Title> with <RERB Code> will expire on <expiration date of approval >. Based on the records of the CGHMC RERB, there had been no communication regarding the progress of this study, which is still in our active file. If the study had been concluded or terminated, kindly fill out a final report form; or if still ongoing, a continuing review form.

Kindly submit the relevant report/form within thirty (30) days of receiving this letter. If no submission is received within the indicated grace period, the committee will be constrained to implement standard procedures for non-compliance with reportorial requirements. This may result in a recommendation for withdrawal of ethical clearance; and the study file subsequently inactivated and archived.

Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the CGHMC RERB Secretariat at (02) 711-4141 local 418.

The CGHMC RERB looks forward to your immediate response and action.

Thank you.

Very truly yours,

<NAME OF CHAIR> Chair, CGHMC RERB

FINAL REPORT (FORM 23)

CGHMC RERB Protocol No.	Approval Date: (dd/mm/yyyy)
Protocol Title	
Principal Investigator	Contact Number
Signature of Principal Investigator	Date Submitted
Total number of participants	No. of Study Arms
Study materials ☐ Drug ☐ Device ☐ Biologic specimen ☐ Others	
Treatment arm	Comparator arm
Study dose(s) of treatment arm	Study dose(s) of comparator arm
Duration of the study	
Objectives	
Results: (Use extra blank paper, if more space is needed)	
RECOMMENDED ACTION: ☐ Uphold Original Approval with No Further Action ☐ Request Information: (Specify) ☐ Recommend Further Action: (Specify)	Type of Review ☐ Full Board ☐ Expedited Meeting Date:
PRIMARY REVIEWER: _____ _____ Signature over name Date RERB CHAIR: _____ _____ Signature over name Date	

DEVIATION / NON-COMPLIANCE/ VIOLATION REPORT(FORM24)

CGHMC RERB Protocol No.	Sponsor Protocol No.	Date of Submission: (dd/mm/yyyy)
Study Title:		
Investigator	Contact Detail/s:	
Sponsor		
Reported by:	Role in study:	
Reason for report: ☐ Participant Non-compliant	☐PI deviation from protocol	
	☐Major	☐Minor
Description:		
Corrective Actions taken by PI/study team		
Preventive Actions taken by PI/ study team		

RECOMMENDED ACTION:	Type of Review
☐No Further Action ☐Request Information: (Specify) ☐Recommend Further Action: (Specify)	☐Full Board ☐Expedited Meeting Date:

PRIMARY REVIEWER: _____ _____
Signature over name Date

RERB CHAIR: _____ _____
Signature over name Date

REQUEST/QUERY RECORD (Form 25)

Date Received by CGHMC RERB: (dd/mm/yyyy)	Received by:
Request from: ☐ Telephone call number ☐ Fax number ☐ Mailed letter/ Date ☐ E-mail/ Date ☐ Walk-in / Date / Time ☐ Others: specify:	
Requesting Party:	Relationship to Participant:
Participant's Name	
Contact Address:	
Title of the Study Participated	
Starting date of Participation	
What are requested?	
Action Taken:	
Outcome:	

SITE VISIT REPORT (FORM 26)

CGHMC RERB Protocol No.		Date of the Visit: (dd/mm/yyyy)	
Study Title:			
Principal Investigator:		Phone:	
Department:		Address:	
Sponsor:		Address:	
Total number of targeted subjects:		Total subjects enrolled:	
Are site facilities appropriate? ☐ Yes ☐ No		Comment:	
Are Informed Consent Forms Recent? ☐ Yes ☐ No		Comment:	
Any adverse events found? ☐ Yes ☐ No		Comment:	
Any protocol non-compliance/ violation? ☐ Yes ☐ No		Comment:	
Are all case record forms up to date? ☐ Yes ☐ No		Comment:	
Are storage of data and investigating products locked? ☐ Yes ☐ No		Comment:	
How well are participants protected? ☐ Good ☐ Fair ☐ Not good		Comment:	
Any outstanding tasks or results of visit? ☐ Yes ☐ No		Give details:	

Other comments:		
Duration of visit: (hours)	Starting from:	Finished at:
Names of CGHMC RERB Site Visit Team		
Completed by:	Date:	

RECOMMENDED ACTION:

☐No Further Action
☐Request Information: (Specify)
☐Recommend Further Action: (Specify)

STUDY TERMINATION (FORM 27)

CGHMC RERB Protocol No.	Sponsor Protocol No.
Protocol Title:	
Principal Investigator:	
Date of Submission	Contact No/ E-mail
Department:	Sponsor
RERB Approval Date:	Date of Last Progress Report:
No. of Participants Screened:	No. of Participants Enrolled:
Reason for Termination	
Summary of results	
Accrual Data:	
Plan for Follow-up for Enrolled participants	
P.I. Signature	Date

RECOMMENDED ACTION: ☐No Further Action ☐Request Information: (Specify) ☐Recommend Further Action: (Specify)	Type of Review ☐Full Board ☐Expedited Meeting Date:
PRIMARY REVIEWER: _____ Signature over name RERB CHAIR: _____ Signature over name	_____ Date _____ Date

ACTION LETTER TO CONTINUING REVIEW APPLICATION / FINAL REPORT/ STUDY PROTOCOL NON-COMPLIANCE REPORT/ SAE REPORT/ EARLY STUDY TERMINATION REPORT/ SITE VISIT

(FORM 28)

Date:

Principal Investigator
Affiliation

CGHMC RERB Protocol No: Sponsor Protocol No.
Protocol Title

Dear <TITLE OF PI> <SURNAME>:

We wish to inform you that the Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) acknowledged receipt of <Continuing Review Application/Final Report / Study Protocol Non-Compliance Report / SAE Report / Site Visit Report> dated <date of document>.

Upon review of < Continuing Review Application Form / Final Report Form / Study Protocol Non-Compliance Report Form / Serious Adverse Event Report Form / Site Visit Report Form > and <submitted document/s>, RERB action is

<REQUEST INFORMATION/RECOMMENDATION FOR FURTHER ACTION>.

Recommended revisions and/or clarifications are summarized below:

Should you have any questions or clarifications regarding the above-mentioned recommendations, please contact the undersigned through the CGHMC RERB Secretariat at (02) 711-4141 local 418.

The CGHMC RERB looks forward to your immediate response and action.

Very truly yours,

<NAME OF CHAIR>
Chair, Research Ethics Review Board
CGHMC

AGENDA OF THE MEETING (FORM 29)

NOTICE OF MEETING

To : CGHMC Research Ethics Review Board Members:

(Name of RERB Member 1) (Name of RERB Member 2)
(Name of RERB Member 3) (Name of RERB Member 4)
(Name of RERB Member 5) (Name of RERB Member 6)

Date of Meeting:
Time of Meeting:
Venue of Meeting:

AGENDA:

1. CALL TO ORDER
2. DETERMINATION OF QUORUM
3. DISCLOSURE OF CONFLICT OF INTEREST
4. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING
5. BUSINESS ARISING FROM THE MINUTES OF THE PREVIOUS MEETING
6. PROTOCOL REVIEW
   - 1.1. New Protocols for review
   - 1.2. Resubmitted Protocols for Modifications
   - 1.3. Protocol for Clarificatory Interview
   - 1.4. Protocol Amendments
   - 1.5. Continuing Review/Progress Report
   - 1.6. Final Reports
   - 1.7. Protocol Deviations
   - 1.8. Early Study Termination
   - 1.9. Site Visit Reports
   - 1.10. SAE/AE Reports
   - 1.11. Queries or Complaints
7. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR
8. OTHER MATTERS

9. ADJOURNMENT

Prepared by:
(Name of CGHMC RERB Member-Secretary)

Approved by:

(Chair, CGHMC Research Ethics Review Board)

MINUTES OF THE MEETING (FORM 30)

(Date)
(Venue)
(Time)

1. ATTENDANCE
   Present: Absent:

2. CALL TO ORDER
3. DETERMINATION OF QUORUM
4. DISCLOSURE OF CONFLICT OF INTEREST (COI)
5. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING
6. BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING
   Matters requiring CGHMC RERB action
7. STUDY PROTOCOL REVIEW
   7.1. New Protocols for Initial Review

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary reviewers	
Technical Review	
Sponsor/ CRO	
Quorum Status	
Conflict of interest	

Assessment of Ethical Issues

Privacy and Confidentiality of data	
Protection Plan	
Vulnerability	
Risks	
Benefits	
ICF process and recruitment	
ICF including translation	

Recommendations
Decision
Approval/ expiration date
Frequency of continuing review (in case of approval)

7.2 RESUBMITTED **PROTOCOLS FOR MODIFICATIONS**

7.2.1.

Protocol code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Quorum status	
Conflict of interest	
Assessment of PI response to initial review	
Recommendations	
Decision	
Approval expiration date	
Frequency of continuing review (in case of approval)	
Protocol Code	

7.3 **PROTOCOL AMENDMENTS**

7.3.1.

Protocol Code	
Protocol Approval Date	
Amendment Submission Date	
Protocol Title	
Principal Investigator	

Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest:	
Assessment of amendment requested	
Recommendations	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

7.4 PROGRESS REPORT/**CONTINUING REVIEW**

7.4.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of progress reported	
Recommendations	
Decision	(Approved, Major Modification, Minor Modification, Disapproved)

7.5 **FINAL REPORT**

7.5.1.

Protocol Code	
Protocol Approval Date	
Report Date	

Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessmentof final report	
Recommendations	
Decision	

7.6 **PROTOCOLDEVIATIONS**

7.6.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of deviation report	
Recommendations	
Decision	

7.7. **EARLYSTUDYTERMINATION**

7.7.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	

Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of risks from early termination	
Recommendations	
Decision	

7.8. **SITE VISIT REPORTS**

7.8.1.

Protocol Code	
Protocol Approval Date	
Site Visit Date	
Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of Site Visit report	
Recommendations	
Decision	(Uphold original approval with no further action, Request information, Recommend further action)

7.9. **SAE/AE Reports**

7.9.1.

Protocol Code	
Protocol Approval Date	

Report Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	
Conflict of Interest	
Assessment of SAEs reported	
SAE	
Submission Date	
Date of SAE	
Date of randomization	
Age	
Sex	
Country	
Nature of AE	
Co-morbidities	
Status	
Recommendations	
Decision	

7.10. **QUERIES OR COMPLAINTS**

7.10.1.

Protocol Code	
Protocol Approval Date	
Application Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/CRO	
Quorum status	

Conflict of Interest	
Assessment of query or complaint	
Recommendations	
Decision	

APPENDICES

8. REPORT OF RESULTS OF EXPEDITED REVIEW

8.1. NEW PROTOCOLS (MINOR RISKS)

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

8.2. PROTOCOLS FOR MINOR REVISION

Protocol Code	
Protocol Submission Date	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

8.3. PROTOCOL AMENDMENTS

Protocol Code	
Protocol Approval Date	

Date of Amendment Submission	
Protocol Title	
Principal Investigator	
Primary Reviewers	
Technical Review	
Sponsor/ CRO	
Decision	(Approval, Major Modification, Minor Modification, Disapproval)

9. OTHER MATTERS
10. ADJOURNMENT

Prepared by:

Signature over Name
CGHMC RERB SECRETARIAT
Date:

Approved by:

Signature over Name
CGHMC RERB Chair
Date:

CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING TO ACCESS CGHMC RERB DOCUMENTS (FORM 31)

I, (Name, Surname) as a non-member of the Chinese General Hospital and Medical Center Research Ethics Review Board, understand that the documents I am given access to by the CGHMC Research Ethics Review Board are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the CGHMC Research Ethics Review Board. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested document	
Reason for request	
Number of copies requested	

RECIPIENT	Signature _____
Date: <dd/mm/yyy>	Name <Title, Name, Surname>
RERB MEMBER - SECRETARY	Signature _____
Date: <dd/mm/yyy>	Name <Title, Name, Surname>

PATIENT INFORMATION SHEET AND ICF (ENGLISH TEMPLATE)
(FORM 32 A)

PATIENT INFORMATION AND INFORMED CONSENT FORM

TITLE OF STUDY : _____

SPONSOR : _(if applicable)_____

NAME OF PRINCIPAL INVESTIGATOR: _____

IMPORTANT: PLEASE READ THE ENTIRE DOCUMENT. DELETE ALL TEXTS IN RED BEFORE SUBMITTING TO THE RERB FOR REVIEW.

This template serves as a guide and may be modified according to your research requirements. This document is for a prospective participant who may not be familiar with scientific/medical terms therefore it is suggested not to use them, if possible, in this document. Use a language that is simple and understandable. Use at least a 12pt font for the entire document.

1. Introduction

Briefly state that you are inviting them to participate in the research you are doing.

I am doing a study about (Describe what the study is about). I would like to invite you to join this study because you (Explain why they are being considered/chosen to participate in the study).

Before you can take part in this study, it is important that you understand what the study involves. Please take time to read the following information carefully and ask any questions that you might have.

2. Purpose of the Study

Explain why you are doing the research in lay terms. The language used must clarify rather than confuse. Do not use technical terms. If you must, then provide an explanation of the technical term in a simple language can be easily comprehended. Use local and simplified terms.

The purpose of this study is to _____.

3. Approximate Number of Participants and the Expected Duration of Your Participation in the Study

The study will take place at Chinese General Hospital and Medical Center (if outside state the place). About (write in numbers not in words) or more participants will be enrolled to participate in the study. Participants must meet all the qualifications to be included. If you are enrolled, the duration of your participation is (Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.).

4. Procedures (Type of Research Intervention)

Briefly state the type of intervention/ procedure that will be undertaken. (e.g. research involves interview, a questionnaire or collection of data/ medical records) Describe research procedures step by step in the simplest way understandable to a lay person. Avoid using scientific/medical terms. If not possible, define or describe such terms so that the participant may understand. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. Do not copy paste study maneuver of the protocol.

During your stay some information collected about you in the course of standard care provided to you by the medical staff may be used for this study. This information includes your medical history, laboratory tests, medications and other chart information. You will be asked to answer a set of questions that would inquire on your medical condition which would last approximately __ mins. Data /information collected is primarily for research purposes. (for observational studies).

Also include follow-up intervals (if relevant)

You will be asked to fill out a survey/ questionnaire which will be provided by your study doctor. This will approximately last for _____ mins. You may answer it by yourself or it can be read to you (if applicable)

(for questionnaire/surveys)

5. Benefits

Describe the benefits the PARTICIPANT may gain by joining the study and not those to which they are entitled regardless of participation. You may include benefits to the individual, benefits to the community in which the individual lives, and benefits to society as a whole as a result of finding an answer to the research question. If there is no direct benefit, you may say so, but there should at least be a benefit to the society.

There will be no additional direct medical benefit to you from taking part in this study. However, with your participation, you will be able to contribute to a better knowledge in the management of _____ in the Philippines. (or the information learned from this study can be used in the future to benefit other people with _____.)

6. Risk

Describe the risk/s or discomfort the study may bring to the participant, what will be done to minimize it. Provide enough information about the risks so that the participant can make an informed decision.

This study is only observational and does not involve drugs, laboratory, medical or surgical procedures outside of the treatment that you are receiving from your attending physician. As such, there will be no additional direct risk to you from your participation much as the same way if you do not participate. for observational studies

7. Compensation If there is no compensation, the standard line is

You will not be paid for joining this study.

8. Voluntary Participation/ Withdrawal from the Study

Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you choose not to participate in this study, you are free to refuse and it will not interfere with your future care. If you join the study and change your mind later, you may withdraw from the study at anytime in the future by informing the study doctor, there will be no penalty or loss of benefits to which you are otherwise entitled, and your future medical care will not be affected.

9. Permission for Review of Records, Confidentiality and Access to Records

Your study doctor will collect information. This information, called data, will be entered without your name, on a data collection form. In all of these data collection forms, a code will replace your name. All the data collected will be kept confidential and will be used only as permitted by this consent form or as required by law.

10. Questions/Information

• If you or your representative(s) have any questions regarding the study (or in case of study related injuries, if study involves any form of intervention or procedures), you should contact your study doctor: Study Doctor's name in BOLD letters , Phone number: _____

• If you or your representative(s) have any questions/ concerns regarding your rights as a research subject, you should contact **Dr. Bernice T. Ong-Dela Cruz,** Chair of the Research Ethics Review Board (RERB) of Chinese General Hospital and Medical Center, Manila, Philippines, Tel: 711-4141 1oc. 418.

11. Consent Signatures

Please remove "side effects" and "research medication" if there is no research medication to be given as part of the study.

Please read this section carefully and if in agreement please sign and date at the bottom of the page.

- I have had sufficient time to consider the information provided and to ask for advice if necessary
- I have had the opportunity to ask questions and have received satisfactory responses to my questions.
- I have been provided the details of the known or foreseeable side effects and risks of the research medication and study procedures that I may receive.
- I understand that I am free to accept or refuse my participation at any time without giving a reason. My decision to accept or refuse my participation will have no effect on my continuing treatment. I understand that I am free to discontinue my participation at any time without giving a reason. My decision to discontinue my participation will have no effect on my continuing treatment. I will keep all my rights to treatment and alternative therapy.
- I agree that the data collected for the study will be used for the purpose described above.
- I understand that I'm not waiving any of my legal rights as a result of signing this consent form.
- I have read and understood this patient information and Informed Consent Form and that I freely give my consent to participate in this study.
- I will receive a signed and dated copy of this Informed Consent Form.

12) I FREELY ACCEPT TO PARTICIPATE IN THIS STUDY

Sign and date at the same time, all party:

Printed Name of Participant _____

Date (to be entered by participant) _____

Signature _____

Printed Name of Study Personnel _____

Obtaining Consent

Date _____

Signature _____

Distribution: original for study doctor, copy to _____(name of participant)

For emergency situations where consent of the participant cannot be obtained the following signature line must be signed:

Printed Name of Participant's Legally Authorized Representative _____

Date (to be entered by participant's Legally Authorized Representative) _____

Signature _____

Relationship to Participant _____

If the participant's legally authorized representative cannot read, the following signature line should be signed:

Printed Name of Witness _____

Date (to be entered by the witness) _____

Signature _____

At any given time an incapacitated adult (e.g. intubated patients, unconscious patients, or patients in emergency situations, or patients with impairment in decision making) may explicitly refuse to participate in or request to be withdrawn from the study. The Investigator must respect the request. Wherever possible, the patient will be informed as soon as possible and his/her consent will be requested for the continuation of participation to the study.

PATIENT INFORMATION SHEET AND ICF (TAGALOG TEMPLATE)
(FORM 32B)

PAMAGAT NG PAG-AARAL : _____

SPONSOR : _(if applicable)_____

PANGALANNG DOKTORNG PANANALIKSIK: _____

TALAAN AT PAHINTULOT PARA SA MGA KALAHOK(PASYENTE)

1. Pakikilahok

Ako ay gumagawa ng pag-aaral tungkol sa _____Iniimbitahan/ inaanyayahan kayo na sumali sa pag-aaral na ito dahil ikaw ay _____.

Bago ka makilahok sa pag-aaral na ito, mahalagang mabasa at maintindhan mo kung ano ang nakapaloob sa pag-aaral na ito. Isinasaad sa kasulatang ito ang lahat ng impormasyong malalaman ninyo tungkol sa pag-aaral. Mangyaring basahin nang mabuti ang impormasyon at magtanong ka ng anumang nais mong itanong.

2. Layunin ng Pag-aaral

Ang layunin ng pag-aaral na ito ay _____

3. Humigit-Kumulang na Bilang ng mga Kalahok at Inaasahang Tagal ng Iyong Pakikilahok sa Pag-aaral

Ang pag-aaral ay isasagawa sa Chinese General Hospital and Medical Center. Humigit kumulang _____ang isasali sa pag-aaral. Para makasali, dapat matugunan ng kalahok ang lahat ng kwalipikasyon. Kapag ikaw ay napabilang sa mga kalahok, ang iyong pagsali ay inaasahang tatagal ng _____.

4. Mga Pamamaraan ng Pag-aaral

Ang inyong doctor ng pananaliksik ay mangongolekta ng impormasyon sa pamamagitan ng pakikipanayam at/o pagsusuri ng medical tsart ng inyong personal datos, medical na kasaysayan, ang mga gamot na binibigay sa inyo at ang pamamaraan ng pag-aalalaga sa inyo. (if applicable)

Ang pagsusuri ng inyong kalusugan ay susubaybayan pagkatapos ng 1 buwan, 3 buwan, 6 na buwan, at 1 taon ng "research doctor:" o "research assistant" sa pamamagitan ng anumang sumusunod na pamamaraan: pakikipanayam sa telepono, sulat o koreo, o personal na pagbisita sa inyong paninirahan o sa ospital sakaling kayo ay madala sa hospital. (as applicable)

5. Mga Benepisyo

Walang direktang benepisyo kayong makukuha sa paglahok sa pag-aaral na ito, ngunit ang inyong paglahok ay maaaring magbigay ng mas sapat na kaalaman sa pag-gagamot ng _____sa ating bansa.

6. Mga Panganib

Ang pag-aaral na ito ay isang obserbasyon lamang na pag-aaral. Ang pananaliksik na ito ay walang kasangkot na karagdagang gamot, laboratoryo, o operasyon na bukod sa tamang pangangalaga na ibinibigay ng inyong "attaneding physician" sa kondisyon ninyo. Walang karagdagang direktong panganib na maidudulot sa inyo ng paglahok sa pag-aaral na ito na higit sa maaaring maransan ng mga hindi lumahok.

7. Kabayaran

Kayo ay hindi babayaran sa pagsali sa pag-aaral na ito.

8. Kusang-loob na Pakikilahok / Pag-alis mula sa Pag-aaral

Kusang-loob ang pakikilahok mo sa pag-aaral na ito. Nasa iyo ang desisyon kung makikilahok ka o hindi. Kung ayaw mong lumahok sa pag-aaral, ikaw ay maaring tumanggi at hindi nito maaapektuhan ang pangangalaga sa iyo. Kung sumali ka sa pag-aaral at nagbago ang isip mo, maari kang umalis sa pag-aaral sa pamamagitan ng pagsasabi sa doktor ng pag-aaral at hindi nito maapektuhan ang pangangalaga sa kalusugan mo.

9. Permiso sa Pagrepaso ng mga Talaan, Paglilihim at Pagkuha sa mga Talaan

Kukuha ang inyong doktor ng pag-aaral ng mga impormasyon. Ang impormasyong ito na tinatawag na datos ay ipapasok sa isang data collection form nang wala ang iyong pangalan. Papalitan ng code ang inyong pangalan sa lahat ng mga data collection forms. Lahat ng mga datos na nakolekta ay papanatilihing lihim at gagamitin lamang hanggang sa ipinahihintulot ng kasulatang ito.

10. Mga Katanungan/Impormasyon

• Kung ikaw o ang iyong kinatawan/mga kinatawan ay mayroong anumang katanungan tungkol sa pag-aaral, ang iyong kakausapin ay si Study Doctor's name in BOLD letters, phone number: _____

- Kung ikaw o ang iyong kinatawan/mga kinatawan ay may katanungan tungkol sa iyong mga karapatan bilang pasyente kaugnay sa pag-aaral, ang iyong kakausapin ay si **Dr. Bernice Ong-Dela Cruz**, Chair ng Research Ethics Review Board ng Chinese General Hospital and Medical Center, Manila Tel: 711-4141 loc. 418.

11. Mga Pirma ng Pagsang-ayon

Basahin nang mabuti ang bahaging ito at kung sumasang-ayon ka ay mangyaring pirmahan at isulat ang petsa sa huling bahagi ng kasulatang ito.

- Ibinigay sa akin ang mga detalye ng mga maaaring di mabuting epekto at mga panganib ng gamot ng pananaliksik at mga pamamaraan ng pag-aaral na maaari kong matanggap.
- Nauunawaan ko na kusang-loob ang aking pagsang-ayon o pagtanggi sa pakikilahok sa anumang oras nang walang ibinibigay na kadahilanan. Ang desisyon ko sa pagsang-ayon o pagtanggi sa pakikilahok ay walang epekto sa patuloy na paggagamot sa akin. Nauunawaan ko na may karapatan akong ihinto ang aking pakikilahok anumang oras nang walang ibibigay na kadahilanan . Ang desisyon kong huminto sa aking pakikilahok ay walang magiging epekto sa patuloy kong paggagamot. Mananatili ang aking mga karapatan sa ibang paggagamot at mapagpipiliang paggagamot.
- Sumasang-ayon ako na ang mga impormasyon na makukuha para sa pag-aaral na ito ay gagamitin para sa layunin na inilarawan sa itaas.
- Hindi mawawala ang anumang karapatan na mayroon ako sa ilalim ng batas sa pagpirma ko sa form na ito.
- Nabasa ko at nauunawaan ang impormasyong iniharap sa Ipinaalam na Kasulatan ng Pahintulot na ito. Binigyan ako ng pagkakataon na makapagtanong tungkol dito at pawang nasagot lahat ang aking mga katanungan.
- Ako ay makakatanggap ng kopya ng pirmado at may petsa na Informed Consent Form/Pahintulot.

12. KUSANG-LOOB NA TINATANGGAP KO ANG PAKIKILAHOK SA PAG-AARAL NA ITO

Pirmahan ng sabay-sabay, (halimbawa parehong petsa), nang lahat ng kalahok.

Isinatitik na Pangalan ng Kalahok/ Pasyente _____

Petsa (Isusulat ng Kalahok) _____

Lagda _____

Isinatitik na Pangalan ng Kawani ng Pag-aaral na humihingi ng Pahintulot _____

Petsa _____

Lagda _____

Pamamahagi: ang orihinal para sa doktor ng pag-aaral, kopya para sa (Kalahok/ Pasyente)

Para sa mga pangyayaring pangmadalian ('emergency'), kapag di makuha ang pahintulot ng kalahok na pasyente ay nararapat idagdag ang sumusunod na linya ng pirma

Isinatitik na Pangalan ng Legal na Kinatawan ng Kalahok/ Pasyente _____

Kaugnayan sa Pasyente _____

Petsa (Isusulat ng Legal na Kinatawan) _____

Lagda _____

Kapag ang legal na kinatawan ng kalahok/pasyente ay hindi nakakabasa, nararapat idagdag ang sumusunod na linya ng pirma:

Isinatitik na Pangalan ng Saksi _____

Petsa (Isusulat ng Saksi) _____

Lagda _____

Confidentiality Agreement Form for Guest Attendees to RERB Meetings

(FORM 33)

I,_____,understand that I am allowed to attend the RERB meeting as a guest or an observer. In the course of this meeting, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take the necessary measures to keep the information as confidential, and to be held responsible if any leak occurred within the sphere of my discretion.

Indicate the details (date and number) of the RERB Meeting(s) attended:

……

……

……

Signature of the Guest or Observer

Date:

PROTOCOL TRACKING FORM

(FORM 34)

Protocol No.	**Department**
Protocol Title:	
Principal Investigator	**Contact No.**

Date	**Particulars**	**IN**		**OUT**	**REMARKS**	**Received by INITIAL**
		FA	FYI			

Legend: FA – For approval
FYI – For information